IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/797,958
Applicant(s)	:	BRUSHEY, Stephen
Filed	:	10 March 2004
Title	:	Anesthesia Conduction Catheter for Delivery of Electrical Stimulus
Art Unit	:	3763
Examiner	:	BOUCHELLE, Laura A.
Docket No.	:	PAT000841-007

DECLARATION OF DAVID GRANER

I, David Graner of Pittsburgh, PA, state as follows:

1. I am a 1978 graduate of Penn State University. I hold a Bachelor of Arts in Science degree.

2. From 1995 to the present, I have worked for Micor, Inc., the assignee of U.S. patent application Serial No. 10/797,958 (hereinafter the "instant application").

3. From 1995-1996, I was a manufacturing technician. My responsibilities included extrusion of tubes used for catheters. That work enabled me to learn about different types of thermoplastics. I worked on catheter assembly, which includes drilling holes in catheters, printing, and forming the tips of catheters in a process called tipping. I also worked on different types of catheters that required the molding of various parts to the catheter.

4. From 1996 to 1997, I was a Purchasing/Shipping Technician. My responsibilities included customer service as well as the purchasing of materials, including various types of thermoplastics, for use in the manufacture of catheters.

5. From 1998 to the present, my responsibilities have included sales, marketing, and research and development. I have worked on numerous R&D catheter projects for Micor. These projects have required that I work directly and closely with physicians in the development of new catheter designs. During these projects, I advised customers of the types of materials and manufacturing steps needed to produce a catheter to meet the customer's needs. My previous experience as a manufacturing technician coupled with my understanding of the characteristics of thermoplastic materials provide me with unique insights into the manufacturing of catheters.

6. Because of the unique position I hold within Micor, I have been sent to various industry meetings which have enabled me to gain a better understanding of how catheters are used. That knowledge enables me to make changes in materials, designs, and manufacturing processes to provide catheters suitable for various end uses in a cost-effective manner. I have

attended regional anesthesia industry meetings of the following groups for the purpose of gaining a better understanding of the use of catheters:

- ASRA: American Society of Regional Anesthesia
- ASA: American Society of Anesthesiologists
- AAOS: American Association of Orthopedic Surgeons
- ESRA: European Society of Regional Anesthesia
- Military Regional Anesthesia Workshops
  - Place catheters in human cadavers
  - Place stimulating catheters in live pigs

7. I have read and am familiar with the instant application.

8. I have read and am familiar with U.S. Patent No. 7,386,341 to Hafer.

9. I am aware that the Patent Office has taken the position that "it would have been obvious to one of ordinary skill in the art at the time of invention to combine the embodiments to modify the end cap shown in Fig. 10 [of Hafer] to have a dome shape as shown in fig. 3 [of Hafer] since the combination is a predictable variation." I disagree with the position of the Patent Office.

10. Fig. 3 of Hafer is reproduced below. Fig. 3 illustrates a catheter in which Hafer's distal tip 72 does not close off the distal end of the catheter sheath 56. In this embodiment, the distal tip 72 has no contact with the sheath 56. It is my opinion that one of ordinary skill in the art would not choose such a distal tip for a close-ended catheter for two reasons.

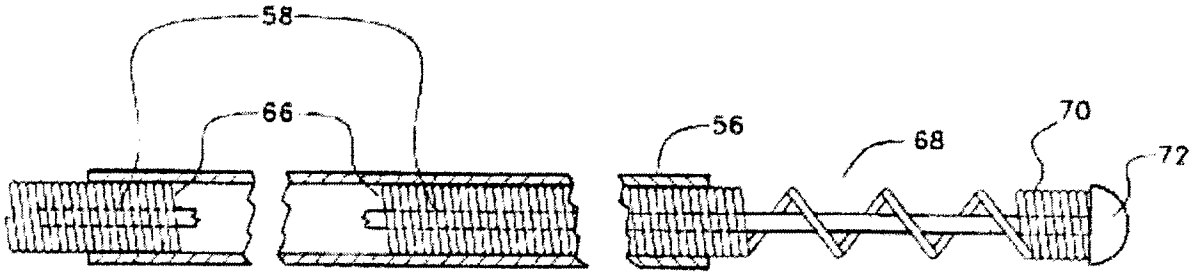
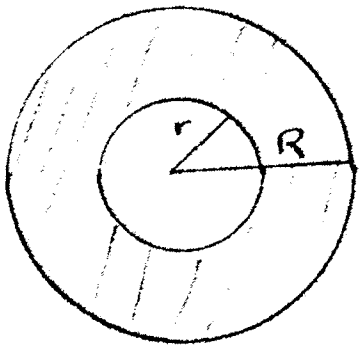


Fig. 3

11. The first reason for not using the distal tip 72 of Fig. 3 of Hafer in a close-ended catheter is the small contact area between the tip 72 and the end face of the sheath 56. Fig. 3 does not provide dimensions, but it appears that distal tip 72 is sized to extend beyond the helical wire 58. The extension of the distal tip 72 beyond the wire 58 is desirable, and to obtain maximum contact between the tip 72 and the end face of the sheath 72, you would provide a tip

with a diameter equal to the outer diameter of the sheath. Using the dimensions in Fig. 5A of the instant application, the maximum contact area between distal tip 72 and the end face of the sheath 72 may be calculated as follows.



$$\text{Area} = \Pi R^2 - \Pi r^2$$

$$\text{Area} = (3.14)(.0175\ \text{in.})^2 - (3.14)(.009\ \text{in.})^2$$

$$\text{Area} = (.000962\ \text{in}^2) - (.000254\ \text{in}^2)$$

$$\text{Area} = .000708\ \text{in}^2$$

12. As seen from the above calculation, the contact area between the tip and the end face of the sheath is very small.

13. The second reason for not using the distal tip 72 of Fig. 3 of Hafer in a closed-ended catheter is that the force exerted by fluid pressure in the catheter is opposite to the adhesion forces holding the distal tip onto the end face of the sheath. That constant opposing force would lead one away from such a configuration.

14. My opinion that a person of ordinary skill in the art would not use the distal tip 72 of Fig. 3 of Hafer in a close-ended catheter is supported by the close-ended embodiments of Hafer. Fig. 10C of Hafer, reproduced below, illustrates a close-ended catheter.

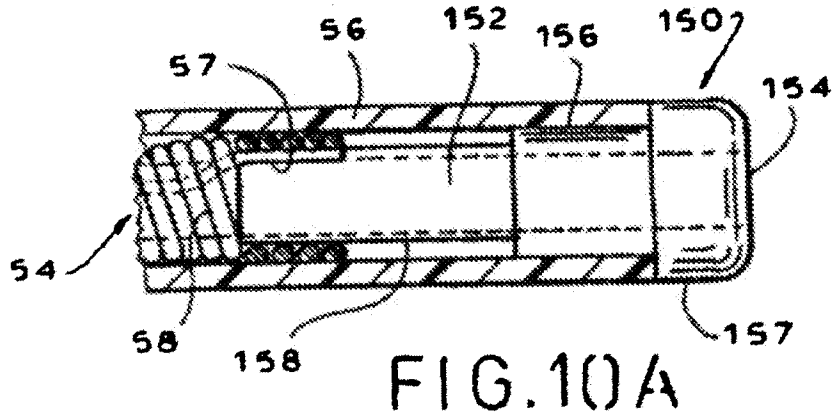
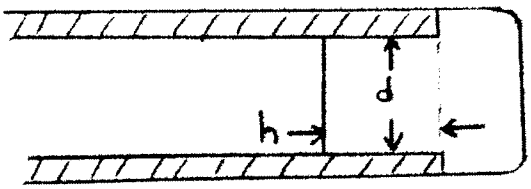


FIG. 10A

15. It is seen in the embodiment of Fig. 10C that the two problems associated with using the distal tip 72 in a close-ended embodiment are overcome by using a T-shaped distal tip.

First, the "stem" portion of the "T" greatly increases the contact area between the distal tip and the sheath. Using exemplary dimensions from Fig. 5A of the instant application, and assuming that the length of the "stem" of the "T" is .016 inches (the same as the maximum weld length in Fig. 5A), the area of contact where the "stem" of the "T" contacts the inner wall of the sheath and the total contact area can be calculated as follows.



Area = Π d h
Area = (3.14)(.018 in.)(.016 in.)
Area = .000904 in^2
Total area = contact with end face of sheath and contact of stem with internal wall of sheath
Total area = .000708 in^2 + .000904 in^2
Total area = .001612 in^2

16. As seen from the above calculation, a "stem" of even modest size more than doubles the contact area between the distal tip and the sheath.

17. The second problem that using a T-shaped distal tip overcomes is that the force exerted by fluid pressure in the catheter is orthogonal to the adhesion forces holding the distal tip to the inside wall of the sheath.

18. Based on the foregoing, it is my opinion that a dome-shaped distal tip is not a predictable variation for use in a close-ended catheter.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 101 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issued thereon.

David Hamer

Dated: 9-04-09